

Message

---

**From:** Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]  
**Sent:** 3/6/2018 7:38:19 PM  
**To:** Doug Spilker [doug.spilker@bayer.com]  
**CC:** Goodis, Michael [Goodis.Michael@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Will Heeb [will.heeb@bayer.com]; Rick Kingston (rkingston@safetycall.com) [rkingston@safetycall.com]; Davis, Kable [Davis.Kable@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]  
**Subject:** RE: Request for meeting to discuss harmonized approach to assigning EPA Severity Codes of adverse effect reports

Good afternoon Dr. Spilker,

We appreciate this commitment to stewardship with pet spot-on products working towards a more harmonized industry-wide approach to severity codes.

I'll follow-up once I am able to touch base with pertinent parties regarding the request for this meeting including the proposed dates and times.

Thank you and have a great day!

Julie

---

**Julie A. Breeden-Alemi, DVM**  
U.S. Environmental Protection Agency  
OCSP / OPP / RD / IVB1  
Breeden-Alemi.Julie@epa.gov  
Phone: 703.347.0511  
Office: S-7216, Mail Code: 7505P

---

**From:** Doug Spilker [mailto:doug.spilker@bayer.com]  
**Sent:** Tuesday, March 06, 2018 10:37 AM  
**To:** Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>  
**Cc:** Goodis, Michael <Goodis.Michael@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Will Heeb <will.heeb@bayer.com>; Rick Kingston (rkingston@safetycall.com) <rkingston@safetycall.com>  
**Subject:** Request for meeting to discuss harmonized approach to assigning EPA Severity Codes of adverse effect reports

Dear Dr. Breeden-Alemi,

Through interactions with the Spot-on Pilot Program participants and in communication with AHI, the Agency has identified that a harmonized approach to assigning EPA Severity Codes of adverse effect reports is a crucial portion of the development of the Agency's signal detection methods and has expressed interest in working with industry toward this approach. In this spirit, Bayer Animal Health and SafetyCall International, Inc. have collaborated to develop common guidelines to assigning EPA Severity Codes, incorporating instructions provided in FIFRA 6(a)(2), guidance from Pesticide Registration Notice 98-3, and suggestions from "Industry's Voluntary 6(a)(2) Incident Reporting Forms and Guidance Documents" prior to FIFRA 6(a)(2) implementation. As both Bayer and SafetyCall are in the process of implementation, we feel it is important to provide these guidelines and discuss our approach with the Agency as this may prove beneficial toward the goal of a more harmonized industry-wide process.

Therefore, Bayer Animal Health would like to meet with the appropriate staff of EPA to share this information. We request a 1-1/2 hour discussion on either the afternoon (any time after 1pm) of Monday, March 19, or Monday, March 26. We request that you invite the appropriate EPA staff.

Attending will be:

- Will Heeb, Manager, Pharmacovigilance, Bayer AH
- Doug Spilker, Manager, EPA Regulatory Affairs, Bayer AH
- Dr. Rick Kingston, SafetyCall International

Thank you for your assistance, and please do not hesitate to call if you have questions.

Best regards,

*Doug*

Douglas A. Spilker, Ph.D.  
Manager, EPA Regulatory Affairs

---

Bayer: Science For A Better Life

Bayer U.S. LLC  
Animal Health R&D, Regulatory Affairs  
P.O. Box 390  
Shawnee, KS 66201  
USA  
Tel: +1 913 268 2751  
Mobile: +1 816 506 3102

E-mail: [doug.spilker@bayer.com](mailto:doug.spilker@bayer.com)

Web: <http://www.bayer.com>

---

*The information contained in this e-mail is for the exclusive use of the intended recipient(s) and may be confidential, proprietary, and/or legally privileged. Inadvertent disclosure of this message does not constitute a waiver of any privilege. If you receive this message in error, please do not directly or indirectly use, print, copy, forward, or disclose any part of this message. Please also delete this e-mail and all copies and notify the sender. Thank you.*

---